



September 26, 2025

Tuned Ltd.
% Shoshana Friedman
Senior Regulatory Affairs Consultant
ProMedoss Inc
6026 Beech Cove Ln
Charlotte, North Carolina 28269

Re: K251208
Trade/Device Name: Tuned Self-Fitting Mobile App
Regulation Number: 21 CFR 874.3335
Regulation Name: Air-conduction hearing aid software
Regulatory Class: Class II
Product Code: SCR
Dated: April 18, 2025
Received: April 18, 2025

Dear Shoshana Friedman:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.

Assistant Director

DHT1B: Division of Dental and ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K251208

Device Name

Tuned Self-Fitting Mobile App

Indications for Use (Describe)

The Tuned Self-Fitting Mobile App is a software-only mobile medical application that is intended to be used with compatible wireless air-conduction hearing aids. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Tuned Self-Fitting Mobile App utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Tuned Self-Fitting Mobile App
510(k) Number K251208

1. SUBMITTER

Applicant's Name and Address:

Tuned Ltd.
18 Harimon St,
Gan Yoshiya
Israel, 3885000

Primary Contact:

Shoshana (Shosh) Friedman
Senior Regulatory Affairs Consultant
Phone: (704) 430-8695
Email: s.friedman@promedoss.com

AND/OR

Bosmat Friedman-Cox
Regulatory Affairs Consultant
Phone: (980) 308-1636 |
Email: bosmat.f@promedoss.com

Date prepared: August 28, 2025

2. SUBJECT DEVICE

Trade Name: Tuned Self-Fitting Mobile App

Classification: **Name:** Air Conduction Hearing Aid Software
Product Code: SCR
Regulation No: 21 CFR §874.3335
Class: 2
Review Panel: Ear Nose & Throat

3. PREDICATE DEVICE

Apple Hearing Aid Feature (HAF) granted under DEN230081.

4. REFERENCE DEVICE

Intrinsound™ Tuned Lumen® 155 Hearing Aids cleared under K223848.

5. DEVICE DESCRIPTION

The Tuned Self-Fitting Mobile App is a software-only, over the counter (OTC) medical application designed to support adults (18+) with perceived mild to moderate hearing loss. Available on both iOS and Android platforms, the app allows users to independently tune and

personalize the settings of compatible wireless air-conduction hearing aids without requiring assistance from a hearing healthcare professional.

The Tuned Self-Fitting Mobile App utilizes calibrated pure-tone audiometry to conduct a self-administered hearing test and computes individualized amplification targets based on the NAL-NL2 prescription algorithm. It automatically configures connected hearing aids according to the results and enables additional fine-tuning by the user through intuitive controls for volume, frequency bands (low/mid/high), and preset sound environments such as everyday use, speech enhancement, music, and outdoor noise reduction.

The reason for this submission is to expand the use of the Tuned Mobile App, which was previously cleared under K223848 for use with the Lumen155 hearing aids (Intricon, USA), to include an additional compatible wireless air-conduction hearing aid, the NoviOne (Novidan, USA).

6. INTENDED USE/INDICATIONS FOR USE

The Tuned Self-Fitting Mobile App is a software-only mobile medical application that is intended to be used with compatible wireless air-conduction hearing aids. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Tuned Self-Fitting Mobile App utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

7. SPECIAL CONTROLS

The Tuned Self-Fitting Mobile App conforms to the special controls stated in 21 CFR 874.3335. These requirements were satisfied through the following:

1. Clinical performance study
2. Non-clinical performance testing
3. Human factors usability studies
4. Software verification, validation, and hazard analysis
5. Labeling

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Tuned Self-Fitting Mobile App is a Software-Only Medical Device (SaMD) that provides self-fitting amplification for individuals with perceived mild to moderate hearing loss. Like the predicate device, the Tuned application is not a hearing aid, but software intended to operate on compatible hardware. While technologically equivalent to the predicate device, from a technological perspective, the Tuned Self-Fitting Mobile App has identical functionalities as the software/App previously cleared as part of the Intrisound™ Tuned Lumen® 155 Hearing Aid under K223848 (reference device); the only difference is that the Tuned Self-Fitting Mobile App is intended as a standalone software that may be utilized with compatible hearing devices.

Table 1 below provides a summarized comparison between the subject device and the predicate and reference devices.

Table 1: Comparison Table

Device	Tuned Self-Fitting Mobile App (Subject Device)	Apple Hearing Aid Feature (HAF) (Predicate Device)	Intrinsound™ Tuned Lumen® 155 Hearing Aid (Reference Device)	Comparison
Submission No.	K251208	DEN230081	K223848	-
Product Code	SCR	SCR	QUH	Same as predicate
Regulation Number	21 CFR 874.3335	21 CFR 874.3335	21 CFR 874.3325	Same as predicate
Intended Use	The Tuned Self-Fitting Mobile App is a software-only mobile medical application that is intended to be used with compatible wireless air-conduction hearing aids. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Tuned Self-Fitting Mobile App utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.	The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.	The Intrinsound™ Tuned Lumen® 155 are self-fitting, wireless air conduction hearing aids, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user’s hearing needs. The device is intended for use without the assistance of a hearing care professional.	Same as predicate
Self-Fitting Strategy	The user adjusts amplification and tuning through a guided self-fitting process.	The user adjusts amplification and tuning through a guided self-fitting process using iOS Health app hearing test data.	The user adjusts amplification and tuning through a guided self-fitting process.	Same as both predicate and reference
Operating System	iOS and Android platforms.	iOS platform.	iOS and Android platforms.	Same as reference; similar to predicate



Tuned Self-Fitting Mobile App

510(k) Summary (Revised)

Device	Tuned Self-Fitting Mobile App (Subject Device)	Apple Hearing Aid Feature (HAF) (Predicate Device)	Intrinsound™ Tuned Lumen® 155 Hearing Aid (Reference Device)	Comparison
Wireless Communication	Bluetooth protocol	Bluetooth protocol	Bluetooth protocol	Same as both predicate and reference
Customization	User-configurable amplification settings for individual hearing needs.	User-configurable amplification settings based on iOS Health app audiogram data.	User-configurable amplification settings for individual hearing needs.	Same as reference; similar to predicate
Labeling	Labeling complies with 21 CFR 800.30(c)(5)	Labeling satisfies the applicable requirements of 21 CFR 800.30	Labeling (of the mobile app) complies with 21 CFR 800.30(c)(5)	Same as both predicate and reference
Validation & Testing	Software performance has been validated per FDA requirements for self-fitting hearing aid software.	Software performance has been validated per FDA requirements for self-fitting hearing aid software.	Software performance has been validated per FDA requirements for Over-The-Counter Self-Fitting Air-Conduction Hearing Aid	Same as predicate
Usability (Human Factors Testing)	A usability study confirmed that users could complete self-fitting without professional assistance. Testing included first-time users in a simulated OTC environment.	Apple conducted usability testing demonstrating that users could successfully complete the self-fitting process using the iOS Health app.	A usability study confirmed that users could complete self-fitting without professional assistance.	Same as both predicate and reference
Hardware Compliance with 21 CFR 800.30	Yes – Tuned Self-Fitting Mobile App is designed to work only with hardware platforms that comply with 21 CFR 800.30.	Yes – Apple HAF was reviewed and granted De Novo classification as compliant with 21 CFR 800.30.	Yes - Intrinsound™ Tuned Lumen® 155 Hearing Aids complies with 21 CFR 800.30.	Same as both predicate and reference

9. PERFORMANCE TESTING

The Tuned Self-Fitting Mobile App, when used with NoviOne hearing aids, has been validated through a series of non-clinical and clinical studies to demonstrate performance equivalence to both predicate and reference devices.

Bench Testing

The Tuned Self-Fitting Mobile went through a series of non-clinical bench testing with representative, compatible hardware to demonstrate that it meets its predefined design input requirements and to address the special controls provided in regulation 21 CFR 874.3335.

The non-clinical testing of the Tuned Self-Fitting Mobile included the following tests:

- Verification of maximum power output (MPO) across compatible hearing aids calibrated using Tuned Self-Fitting Mobile App.
- Verification of the hearing evaluation mode of the Tuned Self-Fitting Mobile App in comparison to ANSI S3.6.
- Verification of Tuned App basic audiometer functions with compatible hearing aids following ANSI S3.6.
- Validation of thresholds obtained from the Tuned App with compatible hearing aids self-test compared to thresholds obtained by standard clinical audiometry.
- Validation of the Tuned self-test and Tuned self-fitting outputs in comparison with professional hearing test and fitting outputs of hearing-impaired participants.
- Real-ear aided responses (REAR) validation of compatible hearing aids powered by Tuned Self-Fitting Mobile App using clinical data.
- Verification of volume and program changes in compatible hearing aids using the Tuned Self-Fitting Mobile App.
- Verification of real-ear outputs during the hearing evaluation mode of the Tuned Self-Fitting Mobile App.

Human Factor/Usability Testing

An additional study was conducted to assess the usability and safety of the Tuned Self-Fitting Mobile App when integrated with the NoviOne hearing aids. The study involved 10 participants representative of the intended user population—adults with perceived mild to moderate hearing loss. The study evaluated participants as they independently performed key tasks including product unpacking, app installation, Bluetooth pairing, self-fitting setup, and ongoing device management using only the provided instructional materials.

Key findings included:

- All participants effectively completed essential onboarding tasks, including application downloading, user account creation, Bluetooth pairing, and initial hearing aid setup. The results confirmed high usability, demonstrating that the onboarding process is accessible and intuitive, even for users with minimal prior technological experience.
- Participants encountered minimal use errors. Observed errors were minor, readily recoverable, and did not lead to any significant harm or safety risks.
- Previously identified usability risks were effectively mitigated through well-designed instructional resources, clear product labeling, step-by-step guided video tutorials, and an

intuitive app interface. The testing confirmed that no new or unmitigated usability risks emerged from integrating this additional hearing aid model to the Tuned Mobile App

Overall, the results demonstrate that the Tuned Self-Fitting Mobile App maintains a prominent level of usability and safety, supporting safe and effective OTC use by adults without the need for professional assistance.

Clinical Testing and Testing using Clinical Data

A clinical audiometric validation was performed to evaluate the comparability of hearing assessment performance between the Tuned App when used with the NoviOne hearing aids and the previously validated Lumen155 configuration (cleared under K223848). This validation demonstrated that the NoviOne configuration delivers threshold measurements substantially equivalent to both professional audiometry and the previously validated Lumen155 system. Mean Absolute Differences (MAD) were all below the clinically significant level of 10 dB, with no statistically significant differences.

The use of the Tuned Self-Fitting Mobile App with the NoviOne hearing aid was validated for Real Ear Aided Response (REAR) performance across input levels of 50, 65, and 80 dB SPL using the same NAL-NL2-based acceptance criteria and MAD methodology applied in the previously cleared Tuned App with Lumen 155. Comparative analysis demonstrated that the self-fitting algorithm consistently met the predefined ± 5 dB acceptance range across all frequencies and input levels when compared to both professional fitting and the previously cleared Lumen 155 self-fitting device.

An additional validation study was conducted to generate perceptual confirmatory data supporting the effectiveness of the Tuned App's self-fitting strategy when used with the NoviOne hearing aids. Using the International Outcome Inventory for Hearing Aids (IOI-HA), the study assessed user-reported benefit and satisfaction after two weeks of real-world use and demonstrated that total scores for the NoviOne configuration were statistically non-inferior to those of both self-fit and professionally fitted Lumen155 configuration.

10. CONCLUSION

The Tuned Self-Fitting Mobile App is substantially equivalent to the Apple Hearing Aid Feature (HAF) predicate device and the mobile app of the Intrisound™ Tuned Lumen® 155 Hearing Aid reference device. Technological differences that exist between the devices are within acceptable margins and/or have been addressed through non-clinical, clinical and usability testing.

Based on the evaluation and the data presented in this submission Tuned Self-Fitting Mobile App is substantially equivalent to the predicate device.